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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 09/775,743      | 02/02/2001  | Lioudmila Tchistiakova | 082181-36154        | 9394             |

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[REDACTED] EXAMINER

CHERNYSHEV, OLGA N

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1646

DATE MAILED: 04/28/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                |                     |
|------------------------------|--------------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>         | <b>Applicant(s)</b> |
|                              | 09/775,743                     | TCHISTIAKOVA ET AL. |
|                              | Examiner<br>Olga N. Chernyshev | Art Unit<br>1646    |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 February 2003.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 43-48 and 56-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 43-46 is/are allowed.
- 6) Claim(s) 47-48, 56-59 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 42 and 49-55 have been cancelled, claims 43-48 have been amended and claims 56-59 have been added as requested in the amendment of Paper No. 15, filed on February 24, 2003. Claims 43-48 and 56-59 are pending in the instant application.

Claims 43-48 and 56-59 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on February 24, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Sequence compliance***

5. Applicant is reminded that the proper form to present a sequence identifier is "SEQ ID NO: X", see section 2 of Paper No. 13. Claims 43, as amended, and claim 56 remain not in compliance with the sequence rules. Appropriate correction is required.

### ***Specification***

6. The substitute specification submitted with Paper No. 15 does not comply with 37 C.F.R. § 1.125 with respect to section s (b) (2) and (c).

37 C.F.R § 1.125 states that

Substitute specification.

- (a) If the number or nature of the amendments or the legibility of the application papers renders it difficult to consider the application, or to arrange the papers for printing or copying, the Office may require the entire specification, including the claims, or any part thereof, be rewritten.
- (b) A substitute specification, excluding the claims, may be filed at any point up to payment of the issue fee if it is accompanied by:
  - (1) A statement that the substitute specification includes no new matter; and
  - (2) A marked up version of the substitute specification showing all the changes (including the matter being added to and the matter being deleted from) to the specification of record. Numbering the paragraphs of the specification of record is not considered a change that must be shown pursuant to this paragraph.
- (c) A substitute specification submitted under this section must be submitted in clean form without markings as to amended material. The paragraphs of any substitute specification, other than the claims, should be individually numbered in Arabic numerals so that any amendment to the specification may be made by replacement paragraph in accordance with § 1.121(b)(1).

The marked up version of the instant substitute specification contains underlined originally presented text, see, for example, page 1, lines 26 and 28. Furthermore, Applicant's marking system to show changes in the marked up version is confusing because it indicates changes within words, see, for examples, page 69 at line 5. Finally, the clean form of substitute specification is not present. Appropriate corrections are required.

***Claim Rejections - 35 USC § 112***

7. Claims 47-48 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record in section 8 of Paper No. 13. Amendment to the claim 47, which substituted "a modified biological agent" for "prodrug" did not obviate this

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ground of rejection because it is not clear what is encompassed by the recitation "prodrug" and how prodrug differs from a "therapeutic agent".

***New grounds of rejection necessitated by amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 56-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 56-59 are directed to a modified peptide capable of specific binding with high affinity VEGF receptor. The instant specification fails to describe a peptide that specifically binds to a high affinity VEGF receptor to the exclusion of binding to any other receptors, for example, other human proteins or other proteins in general. There is no information provided, which would allow one skilled in the art to depict all possible amino acid sequences that lack specific binding sites accountable for specific binding to a high affinity VEGF receptor. There is no knowledge in the prior art that would provide guidance for one skilled in the art on how to exclusively distinguish peptides that lack binding sites responsible for specific binding to the VEGF receptor. There are no working examples that illustrate how to modify a peptide that binds exclusively to a high affinity VEGF receptor and does not bind to any other receptor or a

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polypeptide. Therefore, it would require undue experimentation and making extensive inventive contribution for one skill in the art in order to practice the currently claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 56-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. Claim 56 recites the limitation "a compound of SEQ ID NO. 1". There is insufficient antecedent basis for this limitation in the claim because the relationship between "a compound" and "a modified peptide" is not clear.
11. Claims 57-59 are indefinite for being dependent from indefinite claim.

### *Conclusion*

12. Claims 43-46 are allowed. Claims 47-48 and 56-59 are rejected.
13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative

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number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *OC*  
April 24, 2003

*JL*  
JOHN ULRICH  
PRIMARY EXAMINER,  
GROUP 1600